

§315.6

16 CFR Ch. I (1–1–13 Edition)

(e) *No alteration of prescription.* A seller may not alter a contact lens prescription. Notwithstanding the preceding sentence, a seller may substitute for private label contact lenses specified on a prescription identical contact lenses that the same company manufactures and sells under different labels.

(f) *Recordkeeping requirement—verification requests.* A seller shall maintain a record of all direct communications referred to in paragraph (a) of this section. Such record shall consist of the following:

(1) For prescriptions presented to the seller: the prescription itself, or the facsimile version thereof (including an email containing a digital image of the prescription), that was presented to the seller by the patient or prescriber.

(2) For verification requests by the seller:

(i) If the communication occurs via facsimile or e-mail, a copy of the verification request, including the information provided to the prescriber pursuant to paragraph (b) of this section, and confirmation of the completed transmission thereof, including a record of the date and time the request was made;

(ii) If the communication occurs via telephone, a log:

(A) Describing the information provided pursuant to paragraph (b) of this section,

(B) Setting forth the date and time the request was made,

(C) Indicating how the call was completed, and

(D) Listing the names of the individuals who participated in the call.

(3) For communications from the prescriber, including prescription verifications:

(i) If the communication occurs via facsimile or e-mail, a copy of the communication and a record of the time and date it was received;

(ii) If the communication occurs via telephone, a log describing the information communicated, the date and time that the information was received, and the names of the individuals who participated in the call.

(4) The records required to be maintained under this section shall be maintained for a period of not less than

three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(g) *Recordkeeping requirement—Saturday business hours.* A seller that exercises its option to include a prescriber's regular Saturday business hours in the time period for verification specified in §315.5(c)(3) shall maintain a record of the prescriber's regular Saturday business hours and the basis for the seller's actual knowledge thereof. Such records shall be maintained for a period of not less than three years, and these records must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

§315.6 Expiration of contact lens prescriptions.

(a) *In general.* A contact lens prescription shall expire:

(1) On the date specified by the law of the State in which the prescription was written, if that date is one year or more after the issue date of the prescription;

(2) Not less than one year after the issue date of the prescription if such State law specifies no date or specifies a date that is less than one year after the issue date of the prescription; or

(3) Notwithstanding paragraphs (a)(1) and (a)(2) of this section, on the date specified by the prescriber, if that date is based on the medical judgment of the prescriber with respect to the ocular health of the patient.

(b) *Special rules for prescriptions of less than one year.* (1) If a prescription expires in less than one year, the specific reasons for the medical judgment referred to in paragraph (a)(3) of this section shall be documented in the patient's medical record with sufficient detail to allow for review by a qualified professional in the field.

(2) The documentation described in the paragraph above shall be maintained for a period of not less than three years, and it must be available for inspection by the Federal Trade Commission, its employees, and its representatives.

(3) No prescriber shall include an expiration date on a prescription that is less than the period of time that he or

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she recommends for a reexamination of the patient that is medically necessary.

§315.7 Content of advertisements and other representations.

Any person who engages in the manufacture, processing, assembly, sale, offering for sale, or distribution of contact lenses may not represent, by advertisement, sales presentation, or otherwise, that contact lenses may be obtained without a prescription.

§315.8 Prohibition of certain waivers.

A prescriber may not place on a prescription, or require the patient to sign, or deliver to the patient, a form or notice waiving or disclaiming the liability or responsibility of the prescriber for the accuracy of the eye examination. The preceding sentence does not impose liability on a prescriber for the ophthalmic goods and services dispensed by another seller pursuant to the prescriber's correctly verified prescription.

§315.9 Enforcement.

Any violation of this Rule shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a, regarding unfair or deceptive acts or practices, and the Commission will enforce this Rule in the same manner, by the same means, and with the same jurisdiction, powers, and duties as are available to it pursuant to the Federal Trade Commission Act, 15 U.S.C. 41 et seq.

§315.10 Severability.

The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid, it is the Commission's intention that the remaining provisions shall continue in effect.

§315.11 Effect on state and local laws.

(a) State and local laws and regulations that establish a prescription expiration date of less than one year or that restrict prescription release or require active verification are preempted.

(b) Any other State or local laws or regulations that are inconsistent with

the Act or this part are preempted to the extent of the inconsistency.

PART 316—CAN-SPAM RULE

Sec.

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316.5 Prohibition on charging a fee or imposing other requirements on recipients who wish to opt out.

316.6 Severability.

AUTHORITY: 15 U.S.C. 7701-7713.

SOURCE: 73 FR 29677, May 21, 2008, unless otherwise noted.

§316.1 Scope.

This part implements the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 ("CAN-SPAM Act"), 15 U.S.C. 7701-7713.

§316.2 Definitions.

(a) The definition of the term "affirmative consent" is the same as the definition of that term in the CAN-SPAM Act, 15 U.S.C. 7702(1).

(b) "Character" means an element of the American Standard Code for Information Interchange ("ASCII") character set.

(c) The definition of the term "commercial electronic mail message" is the same as the definition of that term in the CAN-SPAM Act, 15 U.S.C. 7702(2).

(d) The definition of the term "electronic mail address" is the same as the definition of that term in the CAN-SPAM Act, 15 U.S.C. 7702(5).

(e) The definition of the term "electronic mail message" is the same as the definition of that term in the CAN-SPAM Act, 15 U.S.C. 7702(6).

(f) The definition of the term "initiate" is the same as the definition of that term in the CAN-SPAM Act, 15 U.S.C. 7702(9).

(g) The definition of the term "Internet" is the same as the definition of that term in the CAN-SPAM Act, 15 U.S.C. 7702(10).